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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

7590 06/18/2010

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EXAMINER	
HOLT, ANDRIAE M	

ART UNIT	PAPER NUMBER
1616	

MAIL DATE	DELIVERY MODE
06/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/745,243	PARIKH ET AL.	
	Examiner	Art Unit	
	Andriae M. Holt	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,8,9,11,13,14,16-19,21,22,24,31-33,35,36 and 73-76* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicant's request for reconsideration. Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 are pending in the application. Claims 2-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31-33, 35-36, and 73-76 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

The rejection of claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) **is maintained**.

The rejection of claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 under 35 U.S.C. 103(a) as being unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999) **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cherukuri et al. (EP 0,458,751) in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999).

Applicant's Invention

Applicant claims a textured masked particle comprising a) a core containing an active ingredient, b) a first coating layer comprised of a taste masking agent that substantially covers the core, and c) a second coating layer on the surface of the first coating layer. Applicant claims the taste masking agent is comprised of an insoluble film forming polymer. Applicant claims the second coating layer is comprised of i) a water soluble and/or water swellable film forming polymer; and ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. Applicant claims the weight ratio of water soluble and/or water swellable film forming polymer to anti-grit agent in the second coating layer is in the range of about 20:80 to about 80:20.

Determination of the scope of the content of the prior art (MPEP 2141.01)

Cherukuri et al. teach a delivery system for a cyclic amino acid compound which offers reduced bitterness and improved mouthfeel with desirable high temperature stability. Cherukuri et al. teach the delivery system comprises (a) a core material

comprising an cyclic amino acid compound (core containing active ingredient); (b) a first polymeric coating selected form water insoluble materials in an amount from about 5% to about 100% by dry weight of the core material (first coating, insoluble film forming polymer), and (c) a second hydrophobic coating selected from the group consisting of fats, waxes, and mixtures, present in an amount from about 20% to about 400% by dry weight of the combination of the core material and the first hydrophilic coating (page 4, lines 40-48). Cherukuri et al. teach suitable water-insoluble film-forming polymeric materials are selected from ethyl cellulose, cellulose acetate, and cellulose acetate phthalate (water insoluble polymers). Cherukuri et al. teach that ethyl cellulose is a particularly preferred material. Cherukuri et al. teach that also preferred are anionic copolymers based on polymethacrylic and acylic acid esters (page 5, lines 27-38). Cherukuri et al. teach water soluble polymeric materials suitable for preparations include hydrocolloids such as gum arabic, alginates, gelatin, methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose (page 5, lines 39-46) (water soluble polymers). Cherukuri et al. teach the delivery system may be incorporated in a variety of foods, as well as, pharmaceutical preparation such as chewable tablets (page 4, lines 26-28). Cherukuri et al. teach the delivery system may be prepared into tablet form and may be formulated with known tabletting additives, such as excipients. Cherukuri et al. discloses the preparation of the delivery system may be accomplished by a variety of agglomerative and/or coating techniques known in the art. Cherukuri et al. teach that preferably fluidized bed coating may be employed to form the initial core

as well as to apply the first and second coating (page 5, line 58-page 6, lines 1-12) (substantially coating).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Cherukuri et al. do not teach the second coating layer is comprised of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. are added as secondary references.

Kanai et al. teach in preparation example 2, compound 1, crystalline cellulose, corn starch and magnesium stearate were ground and formulated into tablets with use of sugar-coated punch having a radius of 8 mm. Kanai et al. teach that the resulting tablets were coated with a film coating agent consisting of hydroxypropyl methyl cellulose (hydroxypropyl methyl cellulose), polyethylene glycol 6000 (polyethylene glycol), castor oil and ethanol, giving film-coated tablets of the composition (col. 39, lines 20-27).

Uchida et al. teach that the N-2-propenyl-4-[(2-ethylphenyl)amino]-8-methoxyquinoline-3-carboxamide hydrochloride compound, AVICEL, corn starch and magnesium stearate were mixed, polished and then tableted by means of a R10mm punch (for sugar-coated tablets). Uchida et al. further teach the tablets thus obtained were coated with a film comprising hydroxypropyl methyl cellulose (hydroxypropyl methyl cellulose), polyethylene glycol-6000 (polyethylene glycol), castor oil and methanol to prepare film-coated tablets (col. 64, lines 1-19).

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Cherukuri et al., Kanai et al. and Uchida et al. and use a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol as the second layer. Cherukuri et al. teach an active ingredient coated with two layers that provides enhanced masking of bitter flavor characteristic of the active and reduced grittiness (texture masking). Cherukuri et al. teach the layers are a water insoluble film forming polymer layer that masks tastes, wherein the polymer is ethyl cellulose or cellulose acetate. Cherukuri et al. also teaches that some water soluble polymers may be used in the formulation, particularly the same water insoluble polymers cited in the instant application. One skilled in the art at the time the invention was made would have been motivated to use a water soluble polymer such as hydroxypropyl methyl cellulose and an anti-grit agent such as polyethylene glycol as the second coating in the formulations taught by Cherukuri et al. because as evidenced by Kanai et al. and Uchida et al. these ingredients are used to prepare film-coated tablets. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare the coating layers used in the formulations taught by Cherukuri et al.

In reference to the claimed ratios of 20:80 to about 80:20, 50:50, and 60:40 to about 40:60. Kanai et al. and Uchida et al. each teach that hydroxypropyl methyl cellulose and polyethylene glycol are mixed at a 3:1 or 66.7:33.3. This ratio would fall

within the range of 20:80 to about 80:20. In addition, absent data showing unexpected results, as noted in the previous office action, the use of the ratio would be a matter of routine experimentation and optimization. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Claims 2, 4-6, 8-9, 11, 13-14, 16-19, 21-22, 24, 31, 33, 35-36, and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over CA 2,068,366 in view of Kanai et al. (US 4,868,183) and Uchida et al. (US 5,215,999).

Applicant's Invention

Applicant claims a textured masked particle comprising a) a core containing an active ingredient, b) a first coating layer comprised of a taste masking agent that substantially covers the core, and c) a second coating layer on the surface of the first coating layer. Applicant claims the taste masking agent is comprised of an insoluble film forming polymer. Applicant claims the second coating layer is comprised of i) a water soluble and/or water swellable film forming polymer; and ii) an anti-grit agent selected from the group consisting of polyethylene oxide, polyethylene glycol, and mixtures thereof. Applicant claims the weight ratio of water soluble and/or water swellable film forming polymer to anti-grit agent in the second coating layer is in the range of about

20:80 to about 80:20.

Determination of the scope of the content of the prior art (MPEP 2141.01)

CA 2,068,366 teaches a taste-masked free-flowing powder including microcapsules having a particle size of 300 µm or less that includes a core element including at least one pharmaceutically active ingredient; a substantially smooth and continuous microcapsule coating on the core element formed from a coating composition including a water insoluble polymer (page 3, lines 1-11). CA 2,068,366 teaches a taste-masking microcapsule powder composition may be in the form of sprinkles, tablets; including chewable tablets and lozenges. CA 2,068,366 teaches the pharmaceutical composition may be provided in the form of dispersible or effervescent tablets (page 8, lines 12-20). CA 2,068,366 teaches the water insoluble polymer may be selected from ethyl cellulose and cellulose acetates (water insoluble polymers) (page 8, lines 26-32). CA2,068,366 teaches in one embodiment the taste-masked microcapsule coating composition may include the coating composition of a water insoluble polymer, one or more enteric polymer (enteric polymer), an acid-soluble (reverse enteric) polymer, and a partially water soluble polymer (water soluble polymer). CA 2,068,366 teaches the enteric polymer is selected from cellulose acetate phthalate, hydroxypropyl methyl cellulose phthalate (HPMCP), polyvinyl acetate phthalate, or hydroxypropyl methylcellulose acetate succinate (specific enteric polymers) (page 9, lines 19-38). CA 2,068,366 teaches when the microcapsule coating is a sustained release coating the coating may include a water insoluble polymer (water insoluble polymer); an enteric

polymer (enteric polymer) and a partially water soluble component (water soluble polymer) (page 10, lines 4-12). CA 2,068,366 teaches the partially water-soluble component may be selected from hydroxypropyl methylcellulose, polyethylene glycol and mixtures thereof (hydroxypropyl methylcellulose and polyethylene glycol) (page 10, lines 13-18). CA 2,068,366 teaches the modified release core coating contains a water insoluble polymer; an acid-soluble (reverse enteric) polymer and a partially water soluble component (page 10, lines 27-35). CA 2,068,366 teaches the reverse enteric polymer is selected from the acrylate copolymer sold under the trade designation Eudragit E100 or natural polymers such a Chitin (page 11, lines 2-8) (non enteric water soluble polymer). Eudragit E100 is a cationic copolymer based on dimethylaminoethyl methacrylate and neutral methacrylic ester as evidenced by the EUDRAGIT® E100 specification sheet.

CA 2,068,366 teaches the microcapsule compositions may include carriers or excipients (page 11, lines 23-31). CA 2,068,366 teaches the microcapsule composition can be used with acetaminophen, theophylline, ranitidine hydrochloride, and NSAIDS (page 8, lines 2-8). CA 2,068,366 teaches the method for preparing the microcapsules on page 13, lines 1-23).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

CA 2,068,366 does not teach the second coating layer is comprised of a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol or the claimed ratios. It is for this reason Kanai et al. and Uchida et al. were added as secondary references.

The teachings of Kanai et al. and Uchida et al. with respect to the 35 U.S.C. 103(a) rejection is hereby incorporated and are therefore applied in the instant rejection as discussed above.

Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of CA 2,068,366, Kanai et al. and Uchida et al. and use a water soluble and/or water swellable film forming polymer and an anti-grit agent such as polyethylene oxide or polyethylene glycol as the second layer. CA 2,068,366 teaches various formulations of active ingredients/agents formulated with a water insoluble polymer to mask taste. The formulations that are taught by CA 2,068,366 include insoluble polymers that form films, enteric polymers, and water soluble polymers that also form films. One skilled in the art at the time the invention was made would have been motivated to use a water soluble polymer such as hydroxypropyl methyl cellulose and an anti-grit agent such as polyethylene glycol as the second coating because as evidenced by Kanai et al. and Uchida et al. these ingredients are used to prepare film-coated tablets. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare to the active agents with two coatings.

In reference to the claimed ratios of 20:80 to about 80:20, 50:50, and 60:40 to about 40:60. Kanai et al. and Uchida et al. each teach that hydroxypropyl methyl cellulose and polyethylene glycol are mixed at a 3:1 or 66.7:33.3. This ratio would fall within the range of 20:80 to about 80:20. In addition, absent data showing unexpected

results, as noted in the previous office action, the use of the ratio would be a matter of routine experimentation and optimization. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed March 17, 2010 have been fully considered but they are not persuasive. Applicant argues that neither Kanai et al. nor Uchida et al. disclose or suggest the current claimed coated particles or methods of manufacturing coated particles. In response to Applicant's arguments, as noted in the previous office action Kanai et al. and Uchida et al. were used as evidence to teach that a water soluble and/or water swellable film forming polymer and an anti-grit agents such as polyethylene oxide or polyethylene glycol are used as second layers in the preparation of pharmaceutical formulations. The primary references, Cherukuri et al. and CA 2,068,366, teach active ingredient particles that are coated with two layers, a water insoluble polymer and a water soluble polymer. One skilled in the art at the time the invention was made would have motivated to use a water soluble polymer such as hydroxypropyl methyl cellulose and an anti-grit agent such as polyethylene glycol as the second coating in the formulations taught by the primary references because Kanai et al. and Uchida et al. teach these ingredients are used to prepare film-coated tablets.

While, tablets are not particles, the technology of film coating particle or tablets with the same compounds or combinations of compounds is well known and documented in the art. As such, the skilled artisan would have been motivated to try a film-coating formulation that is well-known in the art, especially when the ingredients of the film-coating formulation can be used to prepare the coating layers used in the formulations taught by the primary references, Cherukuri et al. and CA 2,068,366.

In response to Applicant's argument that Kanai et al. and Uchida et al. do not disclose or suggest the current claimed methods of manufacturing coated particles, Kanai et al. and Uchida et al. were used as evidence to teach that a water soluble and/or water swellable film-forming polymer and an anti-grit agents such as polyethylene oxide or polyethylene glycol are used as second layers in the preparation of pharmaceutical formulations. The primary references, Cherukuri et al. and CA 2,068,366 teach the method of manufacturing coated particles. CA 2,068,366 teaches the method for preparing the microcapsules on page 13, lines 1-23. Cherukuri et al. teach the method on page 5, line 58-page 6, lines 1-12.

None of the claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andriae M. Holt whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/John Pak/
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